DEPARTMENT OF THE ARMY
US ARMY MEDICAL DEPARTMENT ACTIVITY
FORT HUACHUCA, ARIZONA 85613

MEDDAC MEMORANDUM 22 February 2005
No. 40-53

Medical Services
MEDICATION MANAGEMENT



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*This revision supersedes MEDDAC Memo 40-51, dated 24 Jan 2001; and MEDDAC Memo 40-53, dated 6 Jan 2004.

**1**. HISTORY: This issue publishes revision of MEDDAC Memos, 40-51, and 40-53.

**2**. PURPOSE: To summarize regulatory guidelines and set forth local Pharmacy and Therapeutics Committee (P&T) approved policies and procedures for the operation of the Pharmacy Service. Contained herein are P&T approved policies and procedures governing the ordering, storing, prescribing, preparation, dispensing, and administration of pharmaceuticals throughout the U.S. Army Medical Department Activity (USA MEDDAC) and U.S. Army Dental Activity (USA DENTAC) Fort Huachuca.

**3.** SCOPE: This memorandum applies to all MEDDAC, DENTAC, and VETCOM, Fort Huachuca personnel involved in ordering, storing, prescribing, preparation, dispensing, or administration - or who are in anyway responsible for pharmaceuticals or pharmaceutical services.

**4.** REFERENCES:

**4.1** AR 40-3, Medical, Dental and Veterinary Care

**4.2** AR 40-7, Use of Investigational Drugs and Devices in Humans and the Use of Schedule I Controlled Drug Substances

**4.3** AR 40-61, Medical Logistics Policies and Procedures.

**4.4** AR 40-66, Medical Record Administration and Health Care Documentation**.**

**4.5** AR 40-68, Clinical Quality Management

**4.6** AR 190-51, Security of Unclassified Army Property (Sensitive and Nonsensitive)

**4.7** Controlled Substances Act of 1970

**4.8** MEDDAC Memo 15-1, Committees and Minutes

**4.9** MEDDAC Memo 40-24, Emergency Response Protocol, Resuscitative Equipment and Supplies Management.

**4.10** MEDDAC Memo 40-131, Management of Regulated Medical Waste (RMW)

**4.11** MEDDAC Memo 40-166, Unacceptable Abbreviation and Symbol List.

**4.12** MEDDAC MEMO 40-385-2, HAZCOM Program

**4.13** Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Manual, current edition.

**4.14** JCAHO, Standards for Ambulatory Care 2004 SAC, Section 1: Medication Management (MM).

**5.** RESPONSIBILITIES:

**5.1** The Chief, Pharmacy Service will:

**5.1.1** Ensure that MEDDAC Pharmacy Service operates as described herein.

**5.1.2** Conduct appropriate oversight in areas outside the pharmacy where medications are stored, reconstituted, administered, or dispensed

**5.1.3** Serve as the author of this policy and/or any other policies or standard operating procedures related to medication management.

**5.2** The Deputy Commander for Health Services (DCHS) *and* Deputy Commander for Clinical Services *(*DCCS) will ensure that personnel assigned to their patient care areas order, store, and manage pharmaceuticals as described herein.

**5.3** The Clinical Department Chiefs will ensure:

**5.3.1** Appropriate health care personnel assigned to patient care areas, order, store and manage pharmaceuticals as described herein.

**5.3.2** Plan, develop and implement Clinic Standard Operating Procedures (SOPs) addressing medication administration procurement, storage and management are current and include the following;

**5.3.3** Appropriate personnel administering medications ensure they are labeled with the following; drug name, strength, and amount and expiration date.

**5.3.4** Guidelines are in place for prescriber notification in the event of an adverse drug reaction or medication error.

**5.3.5** Appropriate health care professional and non physician healthcare providers are trained and competent to administer drugs, and before administering a medication do the following;

**5.3.6** Verifies that medication is stable, based upon visual examination for particulates or discoloration and that the medication has not expired. JCAHO, Standards of Ambulatory Care, 2004 SAC, Section 1: Medication Management. [MM 5.10.4]

**5.3.7** Verifies that there is no contraindication for administering the medication. [MM 5.10.5]

**5.3.8** Verifies that the medication is being administered at the proper time, in the prescribed dose, and by the correct route. [MM 5.10.6]

**5.3.9** Advises the patient or, if appropriate, the patient's family about any potential clinically significant adverse reactions regarding a new medication. [MM 5.10.7]

**5..10** Addresses monitoring of each patient's response to his or her medication according to the clinical needs of the patient and addresses the patient's response to the proscribed medication and actual or potential medication-related problems while the patient is under the direct care of the organization. [MM 6.10.1]

**5.3.11** The clinic has a process to respond to actual or potential adverse drug events or medication errors and that the physician or care provider that is responsible for the patient is notified and appropriate action is taken when an actual or potential adverse drug event is identified.

**5.3.12** Proper storage of controlled, non-controlled and emergency medications

**5.3.13** Red Cross Volunteers may perform duties commensurate with their individual licensing/certification and/or training.

**6.** CONTINUITY OF PATIENT SPECIFIC INFORMATION

**6.*1*** Patient Specific Information (PSI): A minimal set of patient specific information will be available each time a medication is prescribed, administered, or dispensed:

**6.1.1** Age.

**6.1.2** Sex.

**6.1.3** Current medications.

**6.1.4** Significant diagnoses and co-morbidities

**6.1.5** Laboratory values that are relevant

**6.1.6** Allergies and past sensitivities

**6.1.7** Lactation status, pregnancy status, weight/height or any other information as applicable [MM 2.0]

**6.2** Valid sources of patient specific information:

**6.2.1** Where the hard copy medical record is available, clinical staff involved in a given medication action will review the summary list and clinic note for the visit at each site of prescription, administration, or dispensing. The documentation of prescriptions in the patient's medical/dental record will be accomplished IAW AR 40-66. Medications prescribed for outpatients will be annotated on DD Form 2766, Adult Preventive & Chronic Care Flow Sheet and DA Form 5571, Master Problem List. In situations where a medical/dental record is not available, a Standard Form 600, Chronological Record of Medical Care, will be initiated, completed, and submitted to the Patient Administration Division for inclusion in the medical records jacket.

**6.2.2** CHCS generally contains most pertinent patient specific information and may be consulted as a cross-reference for PSI.

**6.3** Transmission of pertinent clinical information to the pharmacist:

**6.3.1** The hard copy medical record does not generally accompany the patient to the dispensing window of the main or refill pharmacies. Therefore, whenever possible the licensed independent practitioner (LIP) will place the diagnosis or symptom for which a given medication is prescribed in the CHCS sig or comment field for medications.

**6.3.2** When indicated to create further understanding, a copy of the summary list and/or clinic note may be handed to the patient to be given to the pharmacist.

**6.3.3** The pharmacist will ask the patient at the dispensing window details that are not clear from the aforementioned sources.

**7.** SELECTION AND PROCUREMENT

**7.1** The Pharmacy and Therapeutics Committee (P&T), determines the criteria for what medications are selected, listed, and procured IAW AR 40-3, Medical, Dental and Veterinary Care. The charter for this committee is located in MEDDAC Memo 15-1, Committees and Minutes. This committee will review medication lists on an annual basis.

**7.2** The criteria used for selection and procurement include indication for use, effectiveness, costs, and risks, including propensity for medication errors, abuse potential, and sentinel events.

**7.2.1** Requests for the addition of a drug to the formulary will be submitted on DD Form 2081, New Drug Request, through the department chief, to the Chief, Pharmacy Service for review by the Pharmacy and Therapeutics (P&T) Committee.

**7.2.2** Each new drug request will be submitted with the following supporting data: medication use evaluation (MUE) criteria; a recommended deletion(s) from the formulary to cover the estimated cost of the requested drug or show institutional cost savings resulting from the addition of the requested drug (decreased drug use, decreased laboratory and/or radiological studies, or other decreased consumption of MTF resources; documentation (i.e. published clinical studies) supporting significant medical benefit of the new agent over current formulary agents.

**7.2.3** The P&T Committee will review each new drug request and determine if it is warranted. If the supporting requirements are not correct, the request will be returned to the submitting prescriber for completion without consideration.

**7.2.4** The physician or his/her representative requesting the new drug may be present at the P&T Committee meeting to discuss the rationale for the new drug request, if possible.

**7.2.5** Drugs recommended for deletion will be presented to the P&T Committee. These drugs will remain on the formulary until the next P&T Committee meeting. Representatives will be responsible for soliciting input from his/her service/department to evaluate the suggested deletion. The P&T Committee will consider the service/department response(s) in making its recommendation to delete, as planned, or retain on the formulary. In the absence of arguments for retaining the drug as a formulary item, the drug will be deleted.

**7.3** *MTF Formulary*: The formulary, which provides current list of medications, is available online at the MTF's *Formulary OneSource* link: http://www.pharmacyonesource.com/fos/default.asp?L=77387&g=2&f=883

**7.4** The Medication Use and Evaluation Committee (MUE) is the organization's vehicle for conducting an annual medication class review to check for emerging safety and efficacy information. The charter for this committee is located in MEDDAC Memo 15-1, Committees and Minutes.

**7.5** Non-formulary medication: LIPs in the organization use a special drug request, RWBAHC Form 474, to obtain medications that are not on the formulary. A MTF Prescriber requesting a drug as a one-time purchase for a specific patient will submit the request on RWBAHC Form 474 signed by the Chief of his/her department, to the Chief, Pharmacy Service for review. The Chief, Pharmacy Service may approve the purchase at that level if deemed appropriate or he may forclinic it to the DCCS. The DCCS may approve the request at this level or he may forclinic it to the MEDDAC Commander for approval/disapproval. The purchase of non-formulary drugs will be limited to medical necessities for MTF patients for which no suitable formulary substitute exists. The MTF LIP must justify the reason(s) why a formulary drug with similar therapeutic qualities will

not be appropriate for the patient. As a minimum, the requesting physician will address therapeutic efficacy, side effect profile, and cost of the non-formulary drug compared to formulary drugs. Total usage of special drugs will be forcliniced to the P&T Committee for final review.

**7.6** Medication shortages and outages. Notification to LIPs and staff occurs from the Chief of Pharmacy or his/her designated representative via e-mail and the *Formulary OneSource* link. In the event of a long term shortage, protocols designed by an ad-hoc Pharmacy & Therapeutics Committee will be implemented and communicated to LIPs and appropriate clinical staff via e-mail and the *Formulary OneSource* link. In the event of a disaster, obtaining medications happens via coordination with allied medical treatment facilities and is rehearsed annually IAW with the organization's Emergency Management Plan (EMP).

**7.7** Emergency Procurement of Drugs: When it is necessary to procure a drug on an emergency basis that is otherwise unavailable from standard sources, procurement will be attempted in the following order: (1) Prime Vendor/Manufacturer emergency order; (2) Local hospitals/Pharmacies; (3) U.S. Army or U.S. Air Force (USAF) clinics in the immediate area; and (4) DPSC Depot on 03 priority supply requests.

**7.8** Use of Medication Samples: Distribution of medication samples at MEDDAC facilities is prohibited and samples will not be used to treat MEDDAC patients.

**8.** STORAGE AND SECURITY

**8.1** Inspection and oversight of areas where medications are stored: [MM 2.20.13] Pharmacy personnel will perform a monthly physical inspection of all drug storage areas; Logistics Division drug storage areas, where medications are stored prior to administration or dispensing, are not included. All clinics will maintain medications IAW their clinic stockage lists. A record of all medication related inspections is maintained in the Pharmacy. Records of the inspections are maintained by the Pharmacy NCOIC. Discrepancies will be reported to the Chief, Pharmacy and Clinic Department NCO responsible for the correction. The Chief of Pharmacy reports the discrepancy(s) to the Deputy Commander for Clinical Services for the MEDDAC or to the Commander of the USA DENTAC, as appropriate.

**8.2** Approved formulary or special purchase medications destined for outpatient use or clinic stock are stocked.

**8.3** Medications are safely stored under conditions delineated by the manufacturer recommendations.

**8.4** Security.

**8.4.1** The Main Pharmacy and PX Refill Pharmacy have an access roster that controls entry into the main pharmacy to designated personnel. The door to this pharmacy is keyed and coded. Those on the access roster must be escorted across this entry point to the areas of medication storage.

**8.4.2** Weekend/Holiday Access Clinic (WHAC) clinic stock: The WHAC clinic has a key controlled medication room where medications are dispensed, administered, stored, and occasionally reconstituted or transferred from bulk sources to smaller containers. Only a designated registered nurse has a key. Only registered nurses and LIPs may enter the medication storage room. Exceptions are: Designated pharmacist for restock and maintenance purposes and the Narcotic Control Officer. Both will be accompanied by a RN during the inspection or inventory process.

**8.4.3** Other clinic stock areas: Clinic stocks of secure medications are also located at the Family Care Clinic, Pediatric Clinic, Military Medicine Clinic, Ray Troop Medical Clinic, Immunization Clinic, Optometry Clinic, Internal Medicine Clinic, General Surgery Clinic, Physical Therapy, Orthopedic Clinic, the Anesthesia Workroom, and the Ambulatory Surgery Procedure Unit (ASPU). Access to locked cabinets is restricted to designated registered nurses, LIPs, and the pharmacy vault technician (See Appendix A, Dispensing of Outpatient Medications from the WHAC.)

**8.4.4** Clinic medication dispensing machines (PICK Points): PICK Points are double locked and may not be accessed by anyone other than pharmacy. The pharmacy technician who stocks these machines on a daily basis has a key to these machines. The Pharmacy NCOIC is the responsible party for Key Control.

**8.5** Storage and security of controlled substances*:* The organization's procedures regarding the storage of controlled substances are covered in Memo 40-52. This policy defines the necessary safeguards in place to prevent diversion.

**8.6** Collection and segregation of contaminated, damaged, and expired medications: [MM 2.20.7] Until they can be properly turned in, these medications are to be segregated from other medications in specially-labeled blue bins in the rear of the Pharmacy.

**8.7** Segregation of "look alike/sound alike" medications: [MM 2.20.6] Medications (for example, Zyrtec and Zantac) that have been identified to be problematic are identified, are marked with a shelf tag and/or identified with a special comment in CHCS under the drug's name. Drugs must be physically segregated from other medications by relocation to a special shelf. Special "look-alike-sound alike" labels are also utilized for additional identification.

**8.8** Medications and chemicals used to prepare medications are stored in a designated compounding area. [MM 2.20.7] Each container is labeled with its native commercial label, which includes contents, expiration dates, and appropriate warnings. Material Safety Data Sheets (MSDS) are also readily available on site and on the internet for chemicals.

**8.9** Management of medications brought into the organization by patients or their families: The facility does not administer or dispense medications brought into the organization by patients or their families from outside the facility.

**9.** STANDARDIZATION AND LIMITATION OF NUMBER AND CONCENTRATION OF MEDICATIONS.

**9.1** The Pharmacy and patient care areas appropriately limit the number of available medications while ensuring that patient care needs are met. The amount and location of medications maintained as clinic stock requires P&T committee approval.

**9.2** Concentrated electrolyte solutions and other high concentration medications: [MM 2.20.9] Concentrated electrolytes are not available as clinic stock. The Pharmacy maintains a limited quantity of these for use for Emergency Drug Boxes and the crash cart.

**10.** EMERGENCY MEDICATIONS:

**10.1** Appropriate organizational leaders and health care professionals have defined

what emergency medications and supplies are available in which patient care areas.

**10.2** All emergency medications are available as ready-to-administer, age-specific, and unit-dose forms where possible (see stocking list for crash carts in MEDDAC Memo, 40-24, Emergency Response Protocol, Resuscitative Equipment and Supplies Management).

**10.3** The next medication for outdate is listed on the outside of the 2 crash carts, , 1 Hyporthermic Cart, 7 ANA Kits, so that the staff can readily determine that the contents are complete and that they are not expired. Each area will have a contents/list available in a book with a contents list on file.

**10.4** After opening a crash cart, the OIC/NCOIC of the patient care area will notify the designated Pharmacy point of contact and CMS, who replaces the used item stock as soon as possible after use.

**10.5** Details of the organization's procedures regarding emergency medications are covered in MEDDAC Memorandum 40-24, Emergency Response Protocol, Resuscitative Equipment and Supplies Management.

**11.** ORDERING AND TRANSCRIBING.

**11.1** The following are means of valid mechanisms for writing a medication order:

**11.1.1** CHCS order entry fields – the preferred mechanism

**11.1.2** Handwritten prescription pads - as a back-up to CHCS, when non-formulary medications are ordered or from non-MTF LIPs who do not have access to CHCS. Prescription Pads (DD Form 1289) are controlled by pharmacy.

**11.1.3** SF 600 clinic encounter - for administration of medications in the clinic only.

**11.1.4** Transmission via FAX machine from non-MTF LIPs.

**11.1.5** Transmission via FAX or hard copy brought in by patient with an encoded prescriber signature from a PDA.

**11.1.6** Stamped prescriptions are discouraged but will be accepted if verified via the prescribing office.

**11.1.7** Verbal Orders: Medications will not be dispensed to an outpatient without receipt of a properly written and authenticated prescription unless a true emergency exists. In cases where a true emergency exists, the pharmacist or nurse may take the order over the telephone. He/she will immediately reduce the verbal order to writing on a prescription blank or SF 600 and repeat the order back to the person originating the order for clarification.

**11.2** The minimum required elements of a medication order are the same regardless of whether CHCS or handwritten orders are used. [MM 3.20.1/2/3] The minimum required elements of a medication order are the following:

**11.2.1** The first and last name of the patient.

**11.2.2** The address and/or telephone number of the patient.

**11.2.3** The prescriber's clinic or service.

**11.2.4** The date the prescription was written.

**11.2.5** The name, strength, quantity, and directions for use.

**11.2.6** The prescriber's name, signature, name/address of the medical treatment facility where the prescription is written, and, if military, social security number, license type, i.e. DDS, MD, NP, etc., grade and branch of service. For off-site LIPs, a DEA number must be recorded IAW Controlled Substances Act 1970.

**11.2.6.1** Authorized Prescriber Verification: Patient drug orders will only be accepted from persons authorized to write prescriptions as specified in AR 40-3 and AR 40-48. A P&T approved prescribing list for all non-physician prescribers (NPPs) will be established. Signature cards of MTF prescribers, with SSNs, will be kept on file in the pharmacy for authentication of prescriptions.

**11.2.6.2** Prescriptions from LIPs unknown at this facility will be verified by the following procedures: If a prescription is received for filling written by an unknown prescriber it is necessary to validate the prescriber information prior to entering it into CHCS. This may be accomplished by one of four procedures: (1) Call the physician's office; (2) Call the credentialing office of the hospital or sponsoring organization of the prescriber; (3) Call the licensing agency in the state where the prescriber practices; or (4) Access a DEA database on the internet.

**11.2.7** The indication for use as part of the prescription order is encouraged whenever possible, especially with patients on multiple medications or comorbid conditions. [MM 11.2.5]

**11.3** Generic Medication Policy: [MM 3.20.4] A policy of generic substitution will be in effect for all drug orders written by MEDDAC/DENTAC prescribers. Prescriptions for multi-source drugs from civilian prescribers marked "do not substitute" may be returned unfilled to the patient. At the discretion of the pharmacist, the prescriber may be contacted to authorize generic substitution. If so, the name of the individual granting authorization will be annotated on the prescription. The P&T Committee may also authorize the substitution of therapeutically equivalent products by the Pharmacy Service without further permission from the U.S. Government employed prescriber.

**11.4** Look-alike or sound-drugs. [MM 3.20.4] For drugs identified as being problematic, the pharmacist will insert a comment that shows up automatically when the LIP enters the order entry data fields. These comments give the LIP a warning that the drug chosen may be confused with another drug. The Pharmacy Service receives notice of look-alike, sound alike drugs from the USP, Facts and Comparisons, and Formulary OneSource.

**11.5** Actions taken with incomplete, unclear, or illegible orders: [MM 3.20.5] If an order is encountered that is incomplete, unclear, or illegible, a pharmacist will contact the ordering LIP by phone, fax, or in person to establish the correctness of the order. Prescriptions with any question of correctness would not be filled until they are clarified with the prescriber.

**11.6** Do not use abbreviations*:* Effective 15 May 2004, RWBAHC no longer accepts outside requests for prescriptions with any of the unacceptable abbreviations or symbols on them. The unacceptable prescription will be returned by the patient to be rewritten by the provider. The same goes for outside prescriptions. A complete list of Unacceptable Abbreviations, Acronyms, and Symbols List may be found at Appendix D.

**11.7** As needed orders:

**11.7.1** Medication dispensing: If an LIP prescribes a "prn" order, a dose range (e.g. 7-4 mg) or time interval (e.g. every 4-6 hours) is included with the order whenever applicable.

**11.7.2** Medication administration: With the exception of the Department of Anesthesia Perioperative Surgery (DAPS) and the endoscopy suite, "prn" medication orders for administration are not used.

**11.8** Standing, hold, automatic stop, resume, titrating, taper, and range orders: These orders are not authorized. The DAPS does not utilize preprinted order sheets from the certified registered nurse anesthetist (CRNA). However, the CRNA may write 'range' orders for pain (i.e., morphine 2-4 mg IV for a total of 10 mg, titrated every 5-10 minutes as needed for pain greater than 5/10.)

**11.9** Compounded drugs and drug mixtures not commercially available: [MM 3.20.6] If the Pharmacy stocks the ingredients, they will compound whenever possible.

**11.10** Medication-related devices: Except for aerochambers with or without masks, pill splitters, and insulin administration devices, the organization does not dispense medication related devices or use these devices in patient care areas for medication administration.

**11.11** Use of investigational drugs: At this time the organization does not dispense or administer investigational medications. If a need arises for such use, AR 40-7 will be followed and Pharmacy Service will be the custodian of such investigational drugs.

**11.12** Herbal products: At this time the organization does not stock, dispense, or administer herbal products. Patients are to be asked if they are taking any herbal or natural products and if so, they will be added to the patient's CHCS profile for reference, even though they are not dispensed at this facility.

**11.13 "**Orders" for medications from the Department of Anesthesia Perioperative Service (DAPS). All such medications are dispensed using the same procedures employed for the dispensing of medications from other patient care areas.

**11.*14*** Blanket reinstatement of previously-written orders: [MM3.20.10] The organization does not allow the blanket reinstatement of previously-written orders. Orders for all medications must be re-written if the patient is transferred from one patient care area to another.

**12**. PREPARATION AND DISPENSING

**12.1** Review of the order**:** [MM 4.10.2]

**12.1.1** Responsibility for review: A pharmacist and/or LIP reviews all prescriptions orders prior to dispensing. At the Weekend and Holiday Access Clinic, the PICK POINT machines, and in clinical areas where medications are administered, an LIP controls the preparation, administration, and dispensing of medications, when on-site pharmacy support is not provided.

**12.2.1** Content of a review*:* [MM 4.10.5] When a prescription is written, a pharmacist or LIP reviews all orders for appropriateness of the drug, its dose, its frequency, its route of administration; contraindications with a patient's medical profile or co-morbid conditions; variation from the organizational criteria for use; and other relevant medication-related issues and concerns.

**12.2.2** The pharmacist or LIP reviews all prescription orders by automatically applying a real-time scan against a database that integrates all Tricare approved pharmacies, which includes all MTF, network, and the national Tricare Mail Order Pharmacy (TMOP). This database provides real time information about therapeutic duplications; real or potential interactions between the prescription and other medications; and real or potential allergies and sensitivities.

**12.2.3** The pharmacist or LIP also reviews the orders for real or potential interactions with food and laboratory values by using an automated printout in conjunction with an interview with the patient.

**12.2.4** Patient concerns, issues, or questions are clarified and resolved with the dispenser before medications are dispensed.

**12.3** Safe preparation of medications: [MM 4.20.1/2/3/4]

**12.3.1** At the main health center during standard operating hours, qualified pharmacists and pharmacy staff prepare all medications in the Main Pharmacy. Parenteral orders which require the addition of one or more drugs to the basic solution will be compounded in the intravenous (IV) room under the supervision of a Pharmacist for all clinical areas.

**12.3.2** In the Weekend/Holiday Access Clinic or out side the main health center, registered nurses under the direct supervision of LIPs are allowed to prepare commonly dispensed oral medication such as pediatric antibiotics, injectable steroids, and certain IV solution additives IAW Appendix E, Preparation of Parental Admixtures by Nurses. Whenever concerns arise, Pharmacy personnel may be contacted after hours and from outside the main health center by contacting the AOD, who will contact the "on-call" Pharmacy personnel.

**12.3.3** Preparation of hazardous medications. [MM 4.20.1/2/3/4] Preparation of hazardous meds for injecting is not currently done. The facility maintains a hazardous drug list and has specific procedures in place to address their storage and use.

**12.3.4** Preparation accuracy in the Main Pharmacy: [MM 4.20.3] For reconstituted oral antibiotics, the pharmacy uses a bar code driven reconstituting device to automatically and accurately prepare.

**12.3.5** Aseptic techniques for preparation in the main pharmacy: Details concerning the standard procedures for aseptic medication preparation will be added in detail in each clinic's medication SOP. (See Appendix F, SOP for the Preparation of Medications in the Sterile Products Area (IV Room.) How these procedures meet the intent of regulatory standards is covered below.

**12.3.6** Training: A designated pharmacy staff instructs other pharmacy staff in aseptic technique and manipulation of items used in the preparation of IV admixtures and other prepared medication.

**12.3.7** Where aseptic medication preparation occurs: [MM 4.20.4] The designated area, currently in room A-28, for product preparation is clean, uncluttered, and functionally separate to minimize the possibility of contamination.

**12.3.8** Use of a laminar flow hood: [MM 4.20.4] A laminar flow hood is used while preparing any intravenous admixture, any sterile product made from nonsterile ingredients, or any sterile product that will not be used within 24 hours.

**12.3.9** The preparer, dispenser, or administrator of prepared medications conduct a visual inspection of these products for integrity prior to dispensing or administration.

**12.4**. Labeling of medication [MM 4.30.1]

**12.4.*1*** Standardization: The organization uses as standardized labeling criteria and procedures using CHCS.

**12.4.2** Medications prepared prior to administration or dispensing: [MM 4.30.1] The main pharmacy pre-packs oral medications prior to dispensing to service the main pharmacy, the Pick Point machines, and the Weekend and Holiday Access Clinic. The pre-packs are appropriately labeled as defined in 12.4.3. Items dispensed as over-the-counter products will bear no label other than that of the manufacturer unless the prescriber changes the directions.

**12.4.*3*** Label content: [MM 4.30.3] Dispensing: Medications dispensed throughout the organization are labeled to identify the medication name, strength, quantity, and expiration date when not dispensed within 24 hours of the order.

**12.4.3.1** Administration: [MM 4.30.3] Medications are administered as soon as possible after their preparation. The organization does occasionally administer medications later than 24 hours, but not to exceed 48 hours, or whatever the stability is according to the manufacturer and/or sterile products compounding literature beyond their intended use. Therefore they are labeled with expiration or “beyond use” dates. For IV admixtures the preparation date and diluent are included.

**12.4.3.2**. [MM 4.30.4] The perioperative area is the only location that requires Pharmacy-prepared medications for multiple patients. The labels of these medications, in addition to the information listed above, includes the location of the patient, directions for use (including route and storage information), and applicable cautionary statements.

**12.5** Dispensing: [MM 4.40]

**12.5.1** Quantities of dispensed medications do not exceed 90 days for non-controlled substances and 30 days for controlled substances. [MM 4.40.1] Exceptions include ADHD medications, phenobarbital, and clonazepam, which are 60 days each. Soldiers preparing for long deployments may be dispensed up to 180 days of most medications, if reasonable and safe.

**12.5.2** Dispensing procedures adhere to applicable law, regulation, licensure, and professional standards of practice. [MM 4.40.2]

**12.5.3** Dispensing in a timely fashion: [MM 4.40.3]

**12.5.3.1** New medications: New medications are filled at the time of dispensing in most cases. Exceptions to this would be if a drug is temporarily out of stock, then it would be filled when the medication arrives.

**12.5.3.2** Refill medications: Refill medications are usually filled at the time of request but are dispensed within 48 hours of filling. Medications not dispensed within 7 days of filling are returned to stock, and the order is marked with an asterisk thereby denoting that the medication was not received by the patient. LIPs also receive a notification through CHCS of patient "nonadherence."

**12.5.3.3** Medications are dispensed in the most ready-to-administer form available. Some medications are re-packaged by qualified pharmacy staff or a licensed repackager. [MM 4.40.4] Some medications may require tablet spitting, in which case patients are provided with a tablet spitting device, and are given specific one-on-one education on dosage and on how to split tablets with written assistance available. This guidance is also on our website as a Formulary Onesource link.

**13**. ACCESS TO MEDICATIONS WHEN THE PHARMACY IS CLOSED. [MM 4.50.1]

**13.1** Urgent circumstances: [MM 4.60.2] The Weekend and Holiday Access Clinic (WHAC), the Military Medicine Clinic, and the Ray Clinic have the capability to dispense medications to patients when the main pharmacy is closed. Medications not stocked at these locations are available from local network pharmacies or in special circumstances from the main pharmacy, which can be opened by the pharmacist staff member who can be accessed via the Pharmacy Call Roster.

**13.2** Emergent circumstances: IAW with MEDDAC 40-146, Plan for Provision of Patient Care Services, emergency care falls outside the scope of the organization.

**14**. RECALL OR DISCONTINUATION PROCEDURES: [MM 4.70] Drug Recall Procedures are outlined in Appendix D, Drug Recall & Defective Medical Materiel Reporting Procedures.

**15.** MANAGEMENT OF RETURNED MEDICATIONS [MM 4.80]

**15.1** Medications nearing expiration or medications that have expired: Clinic stocks will be rotated to minimize loss through expiration. Efforts will be made to return near-dated items to the Pharmacy Service soon enough so that they may be utilized in other areas. In general, medications within 30 days of expiration are returned to the Pharmacy and held by segregating them in the appropriately named blue container by dosage form, until they can be processed by RWBAHC Pharmacy personnel to be forcliniced and processed by the reverse distributor. When a medication is turned in, a pharmacist in the Main Pharmacy has the option to dispense the medication to be used up to the date of expiration. [MM 4.80.1]

**15.2** Unused medications: [MM 4.80.1] Only the Main Pharmacy and the PX Pharmacy will accept unused medications. These medications are held in a designated container that is segregated from the medications in the Pharmacy, until it is disposed of using the same procedures as other hazardous waste IAW MEDDAC Memo 385-2, HAZCOM Program. The bottle with the patient specific information on the label is disposed of in a HIPAA compliant manner.

**15.3** Turn-in of Controlled Substances: Procedure can be found in the Controlled Substances Policy at Appendix H.

**15.3.1.** The Pharmacy Service and Materials Branch are the only activities authorized to accomplish destruction of controlled substances stocks IAW AR 40-61 and AR 40-3. The Chief, Material Branch may destroy controlled substances when authorized by supply messages directing such action. Destruction must be done IAW AR 40-61 and documented.

**15.3.2** Outdated, deteriorated, or excess stocks of controlled substances will be turned-in to the Pharmacy Service on DD Form 1289. This form will be prepared in duplicate by the activity returning controlled substances. The Pharmacy Service will acknowledge receipt of the turn-in by issuing a document number obtained from the Pharmacy Inventory Specialist and by logging the quantity received into the appropriate CHCS controlled drug file. One copy of the turn-in document, with assigned document number, will be returned to the activity and be retained with the controlled substances register as evidence of the turn-in. Activities accounting for controlled substances on DA Form 3349-1 will also have this form annotated by the Pharmacy Service evidencing the turn-in. A copy will be maintained with other receiving documents in the vault records.

**15.3.3** The Pharmacy Service will log returned patient prescriptions in the appropriate CHCS controlled drug file. The prescription number on the returned vial and the patient name will be included in the entry.

**15.3.4** Return of controlled substances to Material Branch may be done only by units authorized to do business with Material Branch IAW AR 40-61**.**

**15.3.5** Controlled substances that are provided for use by patients being air evacuated must be ordered and accounted for in the same manner as controls that are issued at the clinics. Upon reaching destination, the accountable person will turn-in excess controlled substances to the receiving facility and obtain proper receipt forms (DD Form 1150 or DA Form 3161--both are Request for Issue or Turn-In). Alternatively, the person may keep the controlled substance and DA Form 3949-1 and return these to the Pharmacy Service upon their return to the MEDDAC. All documents obtained from a turn-in at another facility will be turned over to the Pharmacy Service upon return of the accountable person.

**15.3.6** Return of Controlled Substances: Controlled substances on hand at the Pharmacy Service that are expired, contaminated or have deteriorated to a point where they are unsuitable for use, will be turned-in to DoD contract return company for possible credit. A copy of the DA Form 3161, Request for Issue or Turn-In, will be appropriately signed, witnessed as required by AR 40-61, assigned a document number, appropriate information entered into the proper CHCS controlled drug file, and the copy will be retained with vault records as evidence of the turn-in.

**16.** ADMINISTRATION :

**16.1.** Who may administer: Only LIPs with specific privileges to do so or RNs, LVNs, LPNs, who have demonstrated the competence to do so, may administer medications. The initial and annual competency based orientation, which is located in each staff's training folder, is the mechanism the organization uses to demonstrate competence.

**16.2** Administration:

**16.2.1** Procedures that occur before administration: The nurse will verify the following: that the medication selected for administration is correct based upon the written medication order and product label [MM 5.10.3]; that the medication is stable based on visual examination for particulates or discoloration and that the medication is not expired [MM 5.10.4]; that there is no contraindication to administration [MM 5.10.5]; that the medication is being administered at the proper time, in the correct dose, and by the appropriate route [MM 5.10.6]. The nurse will advise the patient, or if appropriate, the patient's family about any potential clinically significant adverse reaction or other concerns about administering a new medication [MM 5.10.7]. The nurse will discuss any unresolved significant concerns about the medication with the physician or prescriber, if different from the physician, or relevant staff involved with the patient's care, treatment, or services [MM 5.10.8].

**16.2.2** Procedures for correct administration: See the SOP for Medication Administration.

**16.2.3** Special considerations for administration in the Internal Medicine Clinic, the Occupational Medicine Clinic, and in Diagnostic Imaging, where medications or contrast agents are sometimes administered in conjunction with diagnostic tests, the LIP who has clinical oversight of that particular section must review the patient's medical condition and medication regimen to ensure that they can be safely administered (e.g. administration of IVP contrast during an IVP or albuterol during a PFT. This same LIP is also responsible for responding promptly to any acute adverse events associated with the administration of these medications.

**17.** MONITORING:

**17.1** Administration: [MM 6.10.1/2] All patients who have received medications administered in a patient care area are observed for at least 20 minutes for an adverse drug reaction. A reassessment is done at 20 minutes by the LIP, LVN/LPN, or RN nurse who document in the medical record. Patients with no evidence of an adverse drug reaction are released. If there is evidence of an adverse drug reaction, the clinical support staff will notify the prescriber immediately. [MM 6.20.5] Patients who experience an acute drug reaction at home notify the prescriber through the usual access procedures. If the patient notifies a pharmacist rather than the prescriber, then the pharmacist will contact the LIP so that appropriate follow-up may be arranged.

**17.2** Dispensing: [MM 6.10.3] To monitor the effects of dispensed medication, including first-dose, the LIP's treatment plan will include patient and family education to follow-up for evidence of efficacy, as well as any evidence of an adverse drug reactions (ADR). In select cases the pharmacist will personally monitor patients for efficacy and side effects. This is done via personal and/or phone interview.

**17.3** Adverse Drug Reactions (ADRs):

**17.3.1** [MM 6.20] When a pharmacist or physician receives information indicative of a potential or real ADR, then a DA 4106 is submitted to the Pharmacy and they are given to the ADR pharmacist, who aggregates them and then for clinics them to the Risk Manager.

**17.3.2** Aggregated data regarding ADRs are presented in a variety of forums, including the Risk Management Committee, the Executive Committee of the Professional Staff (ECOPS), the Medical Staff Committee, and the MUE Committee.

**17.3.3** In order to increase the rate of reporting, the pharmacist reviews a representative sample of records from various services, looking for evidence of ADRs. These reviews provide an opportunity to educate LIPs about ADR reporting procedures and add to the quality of collected ADR data.

**17.3.4** The MUE Committee monitors selected drugs for utilization, cost, efficacy, and safety. Typically high-risk, high-cost, high-volume medications are selected for focused monitoring.

**17.3.5** External reporting of ADRs: The organization reports all potential or real ADRs to the appropriate agencies.

**17.4** Medication errors, including prescribing, administration, and dispensing errors: Effective 1 Mar 04, the governing body (MEDCOM) directed our organization to use a contracted commercial database, the MedMarx error reporting database.

**18.** HIGH RISK MEDICATIONS: [MM 7.10]

**18.1** The organization uses the Institution for Safe Medication Practices (ISMP) list of high risk medications as a benchmark for our facility's list. Using internal ADR, medication error, and sentinel event data, certain additional medications may be added to generate an MTF specific list, which is approved by the MUE Committee and reported to the P&T Committee. This list is updated when necessary. The current MTF specific list is available on the Formulary One Source database. The link to the ISMP list on their website is www.ismp.org.MSAarticles/highalert.htm

**18.2** As appropriate to the services provided, the organization develops processes for procuring, storing, ordering, transcribing, preparing, dispensing, administering, and/or monitoring high risk or high alert medications.

**18.2.1** Procuring: No separate process, unless as otherwise suggested by the manufacturer.

**18.2.2** Storing: All high risk medications are segregated from low risk medications.

**18.3.3** Ordering: The pharmacist or pharmacy technician puts special comment lines in CHCS to notify an LIP that the medication being ordered is high-risk; this comment includes specific information needed to optimize the safety of the order.

**18.3.4** Transcribing: The organization does not transcribe orders.

**18.3.5** Preparing: No separate process, unless as otherwise suggested by the manufacturer

**18.3.6** Dispensing: No separate process, unless as otherwise suggested by the manufacturer

**18.3.7** Administration: No separate process, unless as otherwise suggested by the manufacturer

**18.3.8** Monitoring: Select high risk medications are monitored by the MUE Committee when warranted.

**18.4** The organization does not procure, stock, prescribe, dispense, or administer investigational drugs at this time.

**19.** EVALUATION:

**19.1** The organization's evaluating body for medication management is the MUE Committee.

**19.2** The evaluation process focuses on potential patient safety risk points, messages from the governing body and/or local literature sources. The Committee aggregates this data and recommends interventions to optimize safe medication management practices. The reporting format for MUE and P&T reports is the minutes of the MUE Committee.

**The proponent of this memorandum is the Pharmacy Service. Users are invited to send comments on DA Form 2028(Recommended Changes to Publications and Blank Forms) directly to the Commander, USA MEDDAC, ATTN: MCXJ-RX, Fort Huachuca, AZ 85613-7040.**

**FOR THE COMMANDER:**

**OFFICIAL:**

**NOEL J. CARDENAS**
**Major, MS**
**Deputy Commander**
**for Administration**

**Robert D. Lake**
**Information Management Officer**
**DISTRIBUTION: B**

APPENDIX A

**DISPENSING OF OUTPATIENT MEDICATIONS FROM THE Weekend/Holiday After Hours Clinic (WHAC)**

1. PURPOSE: To establish guidelines for the dispensing of outpatient medications from MEDDAC Clinics.

2. SCOPE: This appendix applies to all personnel assigned to or working in MEDDAC clinics dispensing from the Medical Officer Drug (MOD) Cabinet.

3. REFERENCE: AR 40-3, Medical, Dental and Veterinary Care.

4. POLICIES:

a. General:

(1) Only authorized prescribers may dispense medication dispensed from the clinics. The prescriber will check the medication and label and provide the patient with all required counseling. By Federal Law and Army Regulation 40-3, these dispensing functions cannot be delegated/relegated to a non-prescriber.

(2) Only those drugs recommended by the Pharmacy and Therapeutics Committee (P&T) and approved by the Commander, USA MEDDAC, will be dispensed from the clinics.

(3) Drugs will be dispensed only to those patients evaluated by an authorized MEDDAC prescriber in the clinic or by the Dentist on-call.

(4) The Pharmacy Service has personnel on-call to procure medications not stocked in the clinic for necessary patient treatment.

b. Authorization to Dispense: In the clinics, the completed Standard Form 600 is the authorization to dispense all medications, except controlled substances. A written prescription (DA Form 1289) or CHCS entry must be prepared by an authorized prescriber in order to dispense controlled substances and other legend items on formulary.

c. Quantities of Medications Authorized for Issue: Medications dispensed will be limited to prepackaged quantities designated by the P&T Committee or Chief, Pharmacy Service.

d. Supply and Control of Medications.

(1) Medications intended for dispensing from the clinic will be maintained separately from drug stocks intended for in-house use. These medications will be secured in locked cabinets or carts. Medications will not be dispensed from the clinic during hours of pharmacy operation.

(2) Pharmacy personnel will inventory the WHAC cabinet each day and replenish stocks as required. A one-week operating level, as determined by usage history, will be maintained.

(3) Supplies of controlled drugs must be ordered on DD Form 1289 signed by an authorized prescriber or an RN. Controlled substances may be received only by RNs and authorized prescribers assigned to the area ordering the substances. A DA Form 3949 (Controlled Substance Record) will be maintained for each controlled substance ordered. The DA Form 3949 will indicate receipts from the Pharmacy Service and issues to patients.

## APPENDIX B

## PROCEDURES FOR OBTAINING, STORING, AND DISPENSING DRUGS FROM CLINICS

1. PURPOSE: To establish written procedures and policies for the operation of Pharmacy Service activities in connection with units and clinics for the purpose of ensuring that drugs are obtained, stored, and dispensed effectively, and in a manner consistent with federal laws, and Army regulations.

2. SCOPE: This appendix applies to all personnel assigned to or working in Clinics under the control of USA MEDDAC/DENTAC Fort Huachuca.

3. REFERENCES:

a. AR 40-3, Medical, Dental and Veterinary Care

b. AR 40-68, Clinical Quality Management.

c. AR 40-61, Medical Logistics Policies and Procedures.

4. GENERAL. Medication usage within the MEDDAC is based on a formulary recommended by the Pharmacy and Therapeutics Committee (P&T) and approved by the MEDDAC Commander. The MEDDAC Pharmacy Service serves as the primary source of Federal Supply Class 6505 items (drugs), intended for issue to patients, for all MEDDAC Clinics. Medications from other origins will not be dispensed from clinics. The Pharmacy Service also exercises direct technical supervision over the Unit/Clinic/DC drug storage areas and all Pharmacy Service related procedures conducted therein. Pharmacy personnel on a monthly basis will inspect drug storage areas. Training support will be given to Unit/Clinic/DC personnel, when required, either by presentation of class's on-site or individual instruction by on-the-job training at the Pharmacy Service. A record of inspections/liaison visits will be maintained in the Pharmacy. A copy of the inspection results will be provided to the responsible Charge Nurse/OIC/NCO for correction. Noteworthy and repeat discrepancies will be reported to the PI Committee of the servicing health clinic, Deputy Commander Nursing, and to the DCCS, or DENTAC Commander, as required. Telephonic communication with the supporting pharmacy is encouraged should any medication related problem arise.

5. PROCEDURES FOR OBTAINING DRUGS.

a. Preparation and use of CHCS generated stock lists

(1) Non controlled medications will be ordered on a clinic stock list. The Pharmacy Service will honor only orders for medications appearing on the Pharmacy and Therapeutic (P&T) Committee approved Clinic/DC stockage list, and which bear an authorized signature as it appears on a valid DA Form 577 (Signature Card) maintained in the pharmacy.

(2) Clinic Stock List will be prepared by the requesting activity and presented to the pharmacy for filling.

(3) When filling the valid order, Pharmacy Service personnel will indicate the number of units provided and any additional information required to positively identify the items dispensed. If the item ordered is not authorized for issue, "NA" will be listed, or if the item is out of stock "TOS" will be entered by the pharmacy on the CHCS issue sheet. Any item marked with a TOS should be re-ordered at a later date. The pharmacy will provide a new clinic restock sheet, the original order and the issue sheet to the requester upon delivery of order.

b. Use of computer generated bulk drug order sheets.

(1) Orders for bulk drugs may be ordered on a CHCS generated list provided by the Pharmacy Service. An authorized representative must sign the form.

(2) When filling in the computer generated form, the pharmacy personnel will enter this information into CHCS.

(3) The original form will be returned with the filled order.

6. DISPENSING MEDICATIONS.

a. When the prescriber dispenses a drug, he/she will ensure that the patient understands how to take the medication, is aware of significant side effects, and any precautions associated with the drug. To assure accurate identification of patients, at the time they receive prescribed medication, the patient will be required to present his/her valid ID card.

b. Prescribers assigned to Clinics, or DCs may issue any drug on the stockage list that he/she is authorized to write, directly to the patient. Proper annotation must be made in the patient's medical record and CHCS.

c. Only an authorized prescriber may dispense medication from clinics. The prescriber will check and label the medication and provide the patient with all required counseling. By Federal Law and Army Regulation 40-3, these dispensing functions cannot be delegated/relegated to a non-prescriber.

7. CLINIC/DENTAL CLINIC STOCKAGE LIST: The Clinics/Dental Clinics are authorized by the MEDDAC/DENTAC Commander to stock a variety of drugs. Alterations to the stockage list can be accomplished through the P&T Committee. The Clinic/DC authorized stockage list will be kept current and posted in each Clinic/DC drug room. The Clinics/DCs and their supporting Pharmacy share the responsibility for maintaining stockage levels at no more than a 15-day supply. If non-authorized or excess quantities of drugs are found in the Clinics/DCs, they will be transferred to the Pharmacy.

8. STORING DRUGS:

a. Physical Security: The Physical security of pharmaceuticals and related devices at the Clinics/DCs requires close attention due to the large number of patients transiting the facility.

(1) Limited Access Area: The Clinics/DC drug rooms are considered as storage areas to which access is limited to staff members involved in patient care or medically related logistical operations and will not be readily accessible to patients or other personnel. A sign stating "Limited Access Area" will be posted at the entrance, accompanied by a list of personnel authorized to be in the area unescorted. The drug room will be secured with appropriate locks at all times when not staffed by authorized personnel.

(2) Patient Areas: All drugs stored in patient areas (prescriber's offices, treatment rooms, etc.) will be secured in locked cabinets during the absence of authorized clinic personnel. Keys to the cabinet containing prescription drugs must either be maintained in the designated nurse or LIP's possession or in an approved key box.

(3) External drugs and chemicals will be stored separately from internal and injectable drugs.

(4) Drugs will be stored under proper conditions of sanitation, light, temperature, moisture, ventilation, segregation, and security.

(5) Adequate refrigeration will be available in areas maintaining drugs, which require refrigeration and a refrigeration temperature log will be posted. Anytime that the temperature falls outside the range of 35-40 degrees F the pharmacist should be called. Refrigeration units storing large quantities or monetarily significant amounts of drugs will be supplied with emergency power, have a 24 hour alarm system, or be monitored IAW MEDDAC Infection Control SOP. In situations in which drugs requiring refrigeration are exposed to temperatures outside the recommended range and there is a question of usability, call the pharmacy service for instructions. If there is any question as to whether the product is usable or not, assume that it is not until advised otherwise by a Pharmacist.

(6) Multiple-dose vials, which have been entered or reconstituted will be considered usable IAW the manufacturer's expiration date or when the vial is empty or shows obvious contamination. Oral medications will be considered to be expired upon reaching the manufacturer's labeled expiration date, unless there are signs of visible contamination. Single dose vials or ampules may only be opened and used once.

(7) Outdated or otherwise unusable drugs, i.e. unclear labels, items stored under improper climatic conditions etc, will be isolated and returned to the pharmacy as soon as possible.

(8) Only items approved for stockage by the P&T Committee will be stored in clinics.

b. Disposition of Unusable Drugs: All drugs identified as unusable for any reason must be immediately separated from the remaining drug stock and placed in an area designated for such use. A sign reading "Unusable Drugs" will identify this area. Drugs identified for recall or suspension from use will be handled in a likewise manner. These drugs will be turned-in to the servicing pharmacy as soon as feasible.

c. Drug Recall Procedure: In the event of a drug recall, the servicing pharmacy will notify their respective Clinics/DCs by telephone, followed by a hard copy of the recall message. Recalled drugs will be considered unusable drugs and will be disposed of IAW the above instructions unless informed otherwise. See Appendix D.

d. Reporting of Drug Defects/Complaints: When the appearance of any drug shows signs of undergoing a chemical or physical change (i.e. aspirin tablets with an acetic acid odor, tablets or capsules sticking together, becoming discolored or cracked, particulate matter in injectable preparations, etc.), the drug will be considered unusable and will be removed from stock immediately. The responsible individual (OIC/NCOIC) will telephone the pharmacy and describe the problem. The drugs will be turned-in to the Pharmacy as soon as possible. Pharmacy Service personnel will determine the necessity to report or not report the situation to FDA and DMSC IAW AR 40-61.

9. PACKAGING AND LABELING OF PHARMACEUTICALS: Clinics are not authorized to repackage, transfer from one container to another any legend drug item intended for dispensing to a patient. Pharmacy Service personnel will do all drug repackaging. Prescribers may affix Pharmacy generated labels to Over the Counter Items (OTCs) if the drug is to be used differently than stated by the manufacturer's label.

**APPENDIX C**
**DRUG RECALL/DEFECTIVE MEDICAL MATERIAL REPORTING PROCEDURES**

1. PURPOSE: To establish comprehensive procedures for drug recalls and for reporting defective medical material.

2. SCOPE: These guidelines are applicable to all USAMEDDAC Pharmacy Service personnel. It encompasses all drug storage areas wherein drugs obtained from the Pharmacy Services are stored or dispensed from.

3. RESPONSIBILITY:

a. The Pharmacy Inventory Specialist (PIS) is responsible for implementing this policy.

b. During other than normal duty hours, the Chief, Pharmacy Service, Pharmacist-in-charge, or PIS is responsible for implementing the drug recall procedures set forth in this memorandum.

c. The PIS is responsible for obtaining and maintaining USAMMA MMQC messages, follow-up and documentation of actions taken on recalls, and disposition as provided for in this memorandum.

d. Public media may be used in Type I Drug Recalls. The decision to recall drugs dispensed to outpatients will be made by the Chief, Pharmacy Service in coordination with the Deputy Commander for Clinical Services and/or the Commander, USA MEDDAC Fort Huachuca. Discretion will be used during public drug recalls.

4. DEFINITIONS:

a. Class I Drug Recall: A situation in which there is reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death. In the event of a Class I Drug Recall, notify the Chief, Pharmacy Service and the Pharmacist on duty ASAP.

b. Class II Drug Recall: A situation in which the use of, or exposure to a violative product may cause temporary or medically reversible adverse health consequences or when the probability of serious adverse health consequences is remote.

c. Class III Drug Recall: A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences.

d. Pharmacist in charge: The pharmacist responsible for supervising the operation of the pharmacy section. In the absence of a specifically appointed pharmacist in charge, the pharmacist present with the most time in federal service automatically becomes the pharmacist in charge.

e. Technician in Charge: The pharmacy technician so designated or in his/her absence, the senior pharmacy technician present by rank or grade, then by years of federal pharmacy service.

f. Medication Storage Area: Any area, including clinics where pharmaceuticals obtained from the Pharmacy Service are maintained or utilized.

5. POLICIES: SGMMA MMQC messages and SB 8-75 series Supply Bulletins will be maintained on file in the Pharmacy Service IAW AR 40-61. Drug recalls may be initiated from these sources or through information received from U.S. Government agencies or drug manufacturers. The pharmacy Prime Vendor database allows for identification of a specific product's, manufacturer, at any past point in time. The pharmacy service-dispensing database can identify all patients who received the product at that point in time. Patient phone numbers/addresses from the pharmacy database or from patient records enable recall down to the patient level when required (Type I Recall). Type I Drug Recall actions and specifics will be reported at the MEDDAC Safety meetings and will be included in the minutes thereof. Immediately upon notification of a drug recall, by SGMMA MMQC message, MEDCOM, manufacturer, or the FDA, the following procedures will be implemented:

a. The individual receiving the notification will inform the Chief, Pharmacy Service, PIS, NCOIC, or Pharmacist on duty, one of which will verify the information.

b. For Class I Drug Recalls, steps shall be taken in the following order: (Notify Chief, Pharmacy Service ASAP in all cases of Type I Recall regardless of the hour.)

(1) Using Prime Vendor Data Base, ascertain whether or not the pharmacy purchased any of the manufacturer's brand that is being recalled during the time frame covered by the recall. If the answer is no, abort the procedure.

(2) If the answer is yes, inform the Deputy Commander for Clinical Services of the existence of the problem and continue. Run a DUR report from the pharmacy database on the drug being recalled. Make the dates inclusive of the time period covered by the recall. Inform the Deputy Commander for Clinical Services of the number of patients listed on the report and that the Drug recall is being initiated by telephone. Use the Drug Recall Checklist to ensure that all information is transmitted to outpatients.

(3) The Chief, Pharmacy Service will coordinate a message via public media with the Public Affairs Officer (PAO) announcing the details of the recall.

(4) Divide the list among available personnel and begin the telephoning process, checking off the names of patients contacted as you proceed. Those not contacted will be called at various times throughout the following 72 hours until they are reached. If not reached within 24 hours, letters will be mailed to the patient's listed address.

(5) Contact all medication storage areas under pharmacy service jurisdiction, by telephone or in person. Determine if the recalled item is on hand. Negative responses are required. Recalled items will be turned in to the Pharmacy Service on a Bulk Drug Order. Immediately move all on hand stocks of the item being recalled, to include bulk storage, prepackaged items, unit dose items, and automatic prescription counting cell stocks, into the area designated for unusable drugs.

c. If the drug recall is a Class II or III, implement the following steps:

(1) Using Prime Vendor Data Base, ascertain whether or not the pharmacy purchased any of the manufacturer's brand that is being recalled during the time frame covered by the recall. If the answer is no, abort the procedure, if Yes, proceed to the next step.

(2) Notify all drug storage area supervisors to remove all lots of the item in question from their shelves and place them in the unusable drug area. It will be returned ASAP to the servicing pharmacy in a container clearly marked to indicate that the contents are Unusable Drugs.

(3) Recalled drugs will be isolated in a designated area in the Pharmacy Service pending disposition instructions from logistics personnel or in accordance with instructions in the recall message.

(4) A Memorandum for Record (MFR) of actions taken during a drug recall will be prepared and kept on file and reported during the next scheduled MEDDAC Safety meeting. All drug recalls will be documented, even if a negative report is rendered, indicating that none of the item was supplied through the Pharmacy Service.

6. DOCUMENTATION:

a. All SGMMA-MMQC messages will be filed and a logbook will be used to record each message number, the topic of the message, and the actions taken. All messages will be available. Any gaps in the log will be investigated immediately and any missing messages will be obtained from the Logistics Division. Drug recalls received from other sources will be filed in this log in the same manner.

b. The completed Recall Notification Checklist, located at Appendix D, will be attached to the Message and filed with it.

7. MEDICAL DEFECT REPORTING:

a. Procedures: Medical Material Complaints may be submitted on any drug or medical device, regardless of source of supply. Any medical item suspected of being ineffective or unsafe to the patient or staff will be reported on FDA Form 3500.

b. Medical Reports of Deficiency (RODs) on the above will be submitted on Forms SF-361's, SF-364's, and SF-380's as appropriate. RODs will be sent to DPSC-MAMC, 2800 S. 20th Street, Philadelphia, PA.

c. All such actions and outcomes will be reported to the Pharmacy and Therapeutics Committee.

**DRUG RECALL NOTIFICATION CHECKLIST**

**DATE AND NUMBER OF MESSAGE:**

**DATE AND TIME MESSAGE WAS RECEIVED:**

**RECEIVED BY:**

**TYPE OF DRUG RECALL:**
**(I, II, etc>)**

**ITEM RECALLED:**

**Drug:**
**Manufacturer:**
**Lot Number:**
**Expiration Date:**

**NOTIFICATION OF SUPERVISORY PERSONNEL:**

**Name:**
**Date and Time:**

**ACTION DIRECTED BY MESSAGE:**

**VERIFICATION THAT THE ITEM HAS BEEN ISSUED BY THE PHARMACY SERVICE:**

**Date item received:**
**Quantity received:**

**NOTIFICATION OF USA MEDDAC DRUG STORAGE AREAS OF RECALL AND COMMUNICATION OF DISPOSITION INSTRUCTIONS:**

**OTHER MEASURES TAKEN (e.g. Data base screen of outpatient records - Class I Recall only.)**

**RESULTS OF DRUG RECALL:**
**(Product being recalled on hand Y/N)**
**Qty turned-in to log**

**REVIEWED BY AND DATE:**

# APPENDIX D

## Unacceptable Abbreviation and Symbol List

## Do NOT use any of the following when ordering or prescribing:

| Unacceptable Abbreviation | Example | Why Not to Use | What is acceptable practice |
|---|---|---|---|
| Trailing or terminal zero after decimal point | 3.0 mg | Can be mistakenly read as multitudes of the intended amount without notice of the decimal point | Do not use trailing or terminal zeros—write doses as whole numbers |
| | | | |
| Decimal point preceding dose without preceding zero | .5 mg | Can be mistakenly read as multitudes of the intended amount without notice of the decimal | Include the preceding zero (0) before a decimal point when the dose is less than a whole unit |
| | | | |
| Using shorthand or code to refer to duration of doses or days | F5 & X10 | Unclear as to reference to doses or days | Write out |
| | | | |
| Using shorthand or code to that contains dosage interval | Q.D., Q.I.D., Q.O.D. | Can be confused for one another | Write out the word "daily", "four times daily" and "every other day" |
| | | | |
| U (for unit) | 3U | Mistaken as zero, four or cc | Write "unit" |
| | | | |
| IU (for international Unit) | 3IU | Mistaken as IV or 10 | Write "international unit" |

## The following drug abbreviations are not to be used

| Unacceptable Abbreviation | Why Not to Use | What is acceptable practice |
|---|---|---|
| ug for microgram | Mistaken for mg (milligrams) | Write "mcg" |
| | | |
| CPZ (Prochlorperazine (Compazine) | Not commonly known; may be confused with a medication called CPM | Write out the complete drug name |
| | | |
| DPT Demerorol-Phenergan-Thorazine | May be mistaken for DTP; Diptheria, Tetanus, Pertussis | Write out the complete drug name |
| | | |
| HCT Hydrocortisone | May be mistaken for Hydrochlorothiazide | Write out the complete drug name |
| | | |
| MgSO4-Magnesium sulfate | May be mistaken for Morphine Sulfate or Zinc Sulfate | Write out the complete drug name |
| | | |
| MgSO4-Morphine sulfate | May be mistaken for Magnesium Sulfate or Zinc Sulfate | Write out the complete drug name |
| | | |
| ZnS04-Zinc sulfate | May be mistaken for Magnesium Sulfate or Morphine Sulfate | Write out the complete drug name |
| | | |
| Do not shorten names of drugs—example: Nitro Drip | Can be mistaken for other drug names, such as in the example—"Nitro" drip can mean nitroglycerin or sodium nitroprusside | Write out the complete drug name |

## APPENDIX E
## PREPARATION OF PARENTERAL ADMIXTURES BY NURSES

1. PURPOSE: To establish guidelines for the preparation of Parenteral Admixtures by nursing personnel when the Pharmacy Service is closed or when the preparation is needed STAT or in emergency situations.

2. REFERENCES:

a. Trissel, Handbook on Injectable Drugs, Current Edition.

b. Practice Standards of American Society of Health-Systems Pharmacists, most current edition, Minimum Standards for Pharmacies in Institutions, Standard III.

3. PROCEDURES:

a. Patients receiving outpatient recurrent parenteral therapy will be advised to report to the clinic at dose time daily. Patient will be logged in and assessed by RN. Parenteral preparations are mixed by pharmacy, stored at clinic in "medication only" refrigerator when appropriate. Patient will be monitored during and thirty minutes after dose.

b. Work Area and Preparation:

(1) RNs will be instructed in aseptic technique and manipulation of items used in preparation of IV admixtures.

(2) The area selected for preparation should be an area with minimum amount of traffic flow and one that is free of congestion of both personnel and materials.

(3) Hand washing with a suitable antibacterial skin cleanser (Hibiclens, Alcare, etc.) must be accomplished prior to the preparation of parenteral IAW RWBAHC Infection Control Policy.

(4) The counter used for parenteral preparation should be cleaned and disinfected with 70% Alcohol prior to mixing IVs.

(5) Avoid coughing, sneezing, and talking while preparing a product for parenteral administration.

c. Arrangement of Objects in the Preparation Area:

(1) Examine the doctor's order and select the size and quantity of additive, diluent, syringe, needles, etc.

(2) Carefully examine the condition of packaged items, their labels, and expiration dates for any sign of unsuitability.

(3) Clean external surfaces of items, which may have been exposed to dust or other contaminants with 70% Isopropyl Alcohol pads.

(4) Inspect the contents of containers, ampules, vials, etc., for particulate matter, discoloration or other abnormalities. Examine glass containers for cracks.

(5) Check all items for usability.

(6) If math procedures are involved, ensure a double check is done by RN or LIP of all calculations prior to mixing.

(7) Use a new sterile, disposable syringe.

(8) Ampules and vials are cleaned with 70% Isopropyl Alcohol pads. Pat the rubber stopper and/or the ampule neck with the Alcohol pad. Take care to avoid touch contamination of any prepared area.

(9) A five micron filter needle is to be used to withdraw contents from glass ampules. Discard filter needle and select a 20 gauge needle or smaller prior to injecting into piggyback back, or patient.

(10) Refer to the package insert or other published guidelines for the correct reconstitution diluent and carrying solution to be used. Use recommended quantities of diluent and carrying solution.

(11) Ensure that the vial is free of undissolved drug particles, stopper cores, or precipitates prior to drawing into a syringe for injection into the carrying fluid. A filter needle may be used to withdraw the medication if particulate matter is present. If a filter needle is used, replace it with a regular needle prior to step 7.

(12) Disinfect the additive port of the carrying solution bag and rubber closures of vials with 70% Isopropyl.

(13) Inject the proper amount of drug additive aseptically and invert the bag or bottle 3 times to mix the additive. With ports in the upclinic position, squeeze injection ports to discharge any drug additive that might be inside. Remember to invert the bag or bottle at least 3 times to ensure proper mixing of the additive and the carrying fluid.

d. Mixing of more than One Drug in the same Parenteral Solution

(1) Consult with pharmacy personnel if more than one additive is involved. Pharmacy will prepare.

(2) All questions on compatibilities should be referred to Pharmacy Service personnel on-call.

e. Labeling. After the preparation of the parenteral solution, a medication added label will be affixed to the container with the following information:

Name of patient
Medication added
Amount of drug added.
Name of base solution and amount
Date, time, and rate of administration
Date and time prepared and by whom
Expiration date.

(1) Use Cautionary/accessory labels as appropriate

4. When in doubt about anything concerned with making a parenteral solution or any other drug related matter, DO NOT HESITATE to call the Pharmacy Service person on call.

## APPENDIX F

## STANDARD OPERATING PROCEDURES (SOP) FOR THE PREPARATION OF MEDICATIONS IN THE STERILE PRODUCTS AREA (IV ROOM)

1. Hand washing with a suitable antibacterial skin cleanser (Hibiclens, Alcare, etc.) must be accomplished prior to the preparation of parenteral IAW RWBAHC Infection Control Policy.

2. The counter used for parenteral preparation should be cleaned and disinfected with 70% Alcohol prior to mixing IVs.

3. Avoid coughing, sneezing, and talking while preparing a product for parenteral administration.

4. Utilize the appropriate personal protective equipment(PPE) to include head cover, boot/shoe covers/goggles, mask, gloves, or a gown as deemed appropriate by the Chief, Pharmacy Service.

5. Arrangement of Objects in the Preparation Area:

6. Examine the LIP's order and select the size and quantity of additive, diluent, syringe, needles, etc

7. Carefully examine the condition of packaged items, their labels, and expiration dates for any sign of unsuitability.

8. Clean external surfaces of items, which may have been exposed to dust or other contaminants with 70% Isopropyl Alcohol pads .

9. Inspect the contents of containers, ampules, vials, etc., for particulate matter, discoloration or other abnormalities. Examine glass containers for cracks.

10. Check all items for usability.

11. If math procedures are involved, have someone double check all calculations prior to mixing.

12. Use a new sterile, disposable syringe.

13. Ampules and vials are cleaned with 70% Isopropyl Alcohol pads. Pat the rubber stopper and/or the ampule neck with the Alcohol pad. Take care to avoid touch contamination of any prepared area.

14. A five micron filter needle is to be used to withdraw contents from glass ampules. Discard filter needle and select a 20 gauge needle or smaller prior to injecting into piggyback back, or patient.

15. Refer to the package insert or other published guidelines for the correct reconstitution diluent and carrying solution to be used. Use recommended quantities of diluent and carrying solution.

16. Ensure that the vial is free of undissolved drug particles, stopper cores, or precipitates prior to drawing into a syringe for injection into the carrying fluid. A filter needle may be used to withdraw the medication if particulate matter is present. If a filter needle is used, replace it with a regular needle prior to step 7.

17. Disinfect the additive port of the carrying solution bag and rubber closures of vials with 70% Isopropyl Alcohol pads. Do not touch contaminate needles, ports, or vial stoppers.

18. Inject the proper amount of drug additive aseptically and invert the bag or bottle 3 times to mix the additive. With ports in the upclinic position, squeeze injection ports to discharge any drug additive that might be inside. Remember to invert the bag or bottle at least 3 times to ensure proper mixing of the additive and the carrying fluid.

19. When Mixing of more than One Drug in the same Parenteral Solution, consult with pharmacy personnel if more than one additive is involved. All questions on compatibilities should be referred to Pharmacy Service personnel on-call.